

## REMARKS

The Office Action mailed on October 5, 2010, has been reviewed and the comments of the Examiner carefully considered. Claims 1, 5-13 and 20 are pending and currently stand rejected.

### **Rejections under 35 U.S.C. § 103(a)**

All of claims 1, 5-13 and 20 are variously rejected on several bases as allegedly obvious in view of a combination of various prior art references. It is the Examiner's view that the combination of the cited patents would lead one of skill in the art to arrive at the claims in their entirety. Applicants respectfully traverse the Examiner's rejection for the following reasons.

The test which must be met for a reference or a combination of references to establish obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part, the proper test for obviousness:

Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. § 103 ...

[T]he four factual inquires enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations. (MPEP § 2141).

When applying 35 U.S.C. § 103, the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined. MPEP § 2141 II. This test has not been satisfied here for any of the obviousness rejections.

All of claims 1, 5-13 and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over at least Partain et al. (EP0368253) and Britton et al. (US 2003/0007957). However, these two references do not teach or suggest the present invention, neither taken alone

nor together. Furthermore, none of the other cited references teach or suggest the present invention, nor do they cure the deficiencies of the Partain and Britton references.

In part, every obviousness rejection is based on the assertion that Britton teaches that chitosan and oxidized regenerated cellulose (ORC) are functionally equivalent. This is simply not true. The allegation, in the office action, that Britton teaches that “oxidized cellulose and chitosan...are functionally equivalent materials that can be used as solid substrates for wound care materials” is overly broad, and not supported by any facts. In this way, the rejection does not meet the burden required for the Office to establish a *prima facie* case of obviousness.

To begin with, Britton teaches – at most – that chitosan and ORC are equivalent for the specific and narrow purpose of the invention taught by Britton. Specifically, paragraph [0022] of Britton states that the “[C]ommon feature of the above-described group of substrates is the ability to create a gelatinous consistency ranging from semi-liquid to semi-solid when mixed with unactivated platelet-rich plasma.”. This teaching provides no suggestion or motivation to functionally equate chitosan with ORC for any other purpose whatsoever. To do so is even in contradiction to Partain, as discussed below. Beyond this, Britton does not mention, suggest, or refer to chitosan or ORC in any capacity. In this way, Britton can in fact be read as teaching away from Applicants’ claimed invention.

Furthermore, Applicants note that the present claims are directed, in part, to a bioabsorbable substrate. Britton provides no suggestion or discussion of the use of a material that is bioabsorbable, nor does Britton teach or suggest the preparation of a bioabsorbable substrate. In this way, Britton’s mere disclosure of chitosan and ORC is even further removed from the presently-claimed invention.

As admitted in the Office Action, Partain does not teach or suggest ORC in any manner. Furthermore, a reading of Partain, for all it fairly teaches, reveals that Partain focuses on the utility of chitosan aminopolysaccharides to the exclusion of others. In acidic conditions, chitosan is protonated and is thus able to bind to negatively charged surfaces such as mucosal membranes. This is confirmed in column 3, lines 20 – 35 of Partain. This is very different from ORC, which will only form an anionic moiety. Therefore, the teaching of Partain provides no suggestion or motivation to functionally equate chitosan with ORC for any purpose whatsoever.

MPEP § 2141.02(VI) requires that a prior art reference be taken as a whole, for all it fairly teaches. When each of Partain and Britton is taken as a whole, for all it fairly teaches, the

skilled artisan would not find any teaching or suggestion to arrive at Applicants' claimed invention. Furthermore, the evaluation of a prior art reference for purposes of patentability is supposed to be conducted from the point of view of the skilled artisan. A skilled artisan viewing Partain and/or Britton would not find any teaching or suggestion the presently-pending claims.

None of Cullen, Shanbrom, Nimrod, or Gibbins cures the deficiencies of Partain. Accordingly, none of the references, as combined in the Office Action, provides any teaching, suggestion or motivation to arrive at the presently-claimed invention, and therefore, the skilled artisan would not have any reasonable expectation of success in arriving at Applicants claimed invention without the use of improper hindsight reasoning. Consequently, because none of the rejected claims are obvious, as set forth above, Applicants respectfully request withdrawal of the rejections of claims 1, 5-13 and 20 under 35 U.S.C. § 103(a).

#### **Double Patenting Rejection**

1. Claims 1-3 and 20 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 9 and 12 of copending Application No. 10/608,553, in view of Partain. Applicants disagree with the grounds for rejection, in part, for the reasons set forth above regarding the inapplicability of Partain. Therefore, Applicants respectfully submit that the rejection does not apply, and request reconsideration and withdrawal of the rejection.

**Conclusion**

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5809 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5033) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

**BREDA MARY CULLEN ET AL.**

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